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RW

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/134,472 | 08/14/98 | ROSS | D 227662XY4-S |

HM22/0605

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EXAMINER

OWENS JR, H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1623

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DATE MAILED:

06/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/134,472

Applicant(s)

Ross et al.

Examiner

Howard Owens

Group Art Unit

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☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11 and 23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 and 23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Arguments

5 The following is in response to the amendment filed 3/01/00:

An action on the merits of claims 1-11 and 23 is contained herein below.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 Claims 12-22 have been canceled by applicant.

35 U.S.C. 112

112(1)

20 The rejection of claims 1-11 and newly added claim 23 under 35 U.S.C. 112(1) is maintained for the reasons of record.

25 Applicant's arguments based on the issuance of other patents with regard to vision are not seen as supportive to rebutting the rejection and factors thereof set forth in the office action mailed 3/1/99 regarding the instant specification and instant claims. Applicant's arguments are not convincing in showing that the breadth of the instant claims are adequately and fully
30 supported by the instant specification. 35 U.S.C. 112(1) requires that "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which
35 it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention".

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In the case of the instant specification, there is not seen adequate representation wherein the compounds of the invention are administered to diverse *in vivo* systems, i.e. human, birds, fish, reptiles, etc. and memory is enhanced or treatment of impairment is demonstrated in those with or without the various disorders correlated with sufficient data or guidance to memory and vision functions *in vivo*. Comparing the court's position on the efficacy of a treatment for a single disease in humans based on mice data, certainly does not validate the breadth of the instant claims wherein a multiplicity of visual disorders in a multiplicity of *in vivo* systems is set forth without commensurate support from the specification.

Applicants sole animal model utilized mice and the improvements to memory were confined to that of spatial memory. However, there is not seen adequate representation wherein dosages for diverse animal species was given and disorders such as Alzheimer's, amnesia, Korsakoff's syndrome, etc. have been treated with the compounds of the invention and an improvement in the disorder was demonstrated. Applicant cites the McNamara et al., *Brain Res. Rev.*, reference as support for the broad claim terminology of improving memory or treating memory impairment. However, applicant's attention should be drawn to p. 44, column 1, paragraph 3 - column 2, line 12, wherein McNamara teaches that "First there are many processes involved in learning any performing any learning task, any of which may be impaired by a particular manipulation and only some of which are truly mnemonic processes.....it is important to discriminate between the multiple stages of learning and memory, be they divided into three stages (acquisition, retention, retrieval or more.....The point is that understanding the neurochemical substrates of learning and memory may require the analysis of actions on each

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of many individual processes and that identification of a drug's actions as being specific to acquisition or retention may only be an initial (though essential) step." Thus McNamara recognizes limitations there are inherent to the Morris maze test given the complexity of the concept of memory, given this one can not assume that a compound successful for one stage may be successful for all types and stages of memory nor make the assumption that a variety of etiological factors will find treatment with a given compound or class thereof.

Given that the visual systems vary between animal species as well as the multitude of vision disorders arising from various etiologies, a claim to the treatment of vision disorder or improving vision should be supported with adequate representation commensurate to the breadth and scope of the claim(s). The examples cited by applicant to support the claims cited supra are not treatments, but rather suppositions that if the compounds of the invention are administered to various visual disorders such as uveitis, conjunctivitis, chronic exposure to ultraviolet light an improvement is expected. This is not seen as sufficient guidance or adequate representation(s) to support the treatment claims cited supra. Without the benefit of protocols for a diversity of animal systems such as dosages, routes of administration, one of skill in the art would be subject to undue experimentation in the practice of the invention.

112(2)

Applicant's arguments have been considered, however, the rejection of claims 1-11 under 35 U.S.C. 112(2) is maintained for the reasons of record.

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Claim 11 recites the limitation "compounds 1-25,27,28,31-33 and 35-136 of Tables I, II and III" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of
10 the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing
15 date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, Gary Geist can be reached on (703) 308-1701 . The fax phone number for this Group is (703) 308-4556.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens

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GARY GEIST
SUPERVISORY PATENT EXAMINER
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